REMARKS

This application has been amended in a manner believed to place it in condition for allowance at the time of the next Official Action.

Claims 72-83, 85-90 and 122-128 are pending in the application. Claims 72-75, 77, 88 and 122-124 have been amended to address formal matters raised in the outstanding Official Action. New claims 125-128 have been added. Support for the changes to the claims and new claims 125-128 may be found generally throughout the specification and the original claims. In particular, the Examiner's attention is respectfully directed to Figures 15-25, 49-50 and in the specification on page 41, lines 25-31.

In the outstanding Official Action, claims 72, 73 and 88 were objected to for allegedly containing several informalities. Applicant notes with appreciation the suggestions of the Examiner as how to correct these informalities. However, as the specification refers to the term "fixing position", applicant has elected to amend the claims so that the claims refer to a "fixing position" as opposed to an "inserted position". However, the Examiner is certainly invited to contact the undersigned if the Examiner does not believe that this solution addresses his concerns. Applicant believes that the claims have been amended to address the additional objections identified by the Examiner.

Claims 72-75, 77, 88 and 123-124 were rejected under 35 USC 102(b) as allegedly being anticipated by SHILEY. This rejection is traversed.

Claim 72 recites several structural features. The structural features are as follows:

a) the arm "is attached (or 'fixed' in case of amendment) by one end to the tubular element";

b) "the arms and pins are, in the insertion position, essentially located inside the lumen of the tubular element", i.e. the lumen of the tubular element to which the arms are attached/fixed;

c) "the lumen is provided through the tubular element"; and

d) "the lumen and valve prosthesis are adapted/shaped for accommodation of the valve prosthesis inside the lumen" respectively "the valve prosthesis comprising a cylindrical outer body fitting (in the lumen of) said tubular element"

Taking into account these four structural features, it clearly follows that SHILEY does not anticipate or render obvious the claim 72.

Interpretations of the tubular element of Claim 72

According to SHILEY, the inner ends of the wires 50 are inserted into the retaining/retention points 41 formed by apertures of the inner ring 12 (see column 7, lines 42-45).

Thus, it is the inner ring which carries the inner ends of the (arms of the) wire pins 13.

From this interpretation it follows that the outer ring 11, 111 of SHILEY can not be considered to be the tubular element of Claim 72.

Moreover, it follows that to be comparable with Claim 72, the inner ring 12, 112 of SHILEY must be (part of or portion) the tubular element.

As a result, this leaves only two possible interpretations for the tubular element

1) the inner ring 12, 112 alone is to be considered as the tubular element of Claim 72; or

2) the assembly of inner ring 12, 112 and outer ring 11, 111 is to be considered as the tubular element of Claim 72.

Interpretation of the lumen of Claim 72

Starting from the interpretation that the inner ring 12, 112 alone is to be considered as the tubular element of Claim 72, it is clear that the space defined between the cylindrical inner wall of the inner ring 12, 112 is to be considered as the lumen of Claim 72. Following this interpretation, the difference between SHILEY and Claim 72 is clearly that according to SHILEY the wires 50 and wire pins 35 lie at any time at the outside of the inner ring/tubular element both in the insertion position (see Fig. 5) as well as in the fixing position (figure 6). This means that, following this interpretation, SHILEY does not

disclose or suggest structural feature b) "the arms and pins are, in the insertion position, essentially located inside the lumen of the tubular element".

Furthermore, if one was to adhere to this interpretation, the assembly of inner ring 12, 112 and outer ring 11, 111 would be considered as the tubular element of Claim 72. It is again the space defined between the cylindrical inner wall of the inner ring 12, 112 which is to be considered as the lumen of Claim 72. As explained in the preceding paragraph this means that SHILEY does not disclose the above mentioned structural feature b) "the arms and pins are, in the insertion position, essentially located inside the lumen of the tubular element".

From the Office Action, it appears the space formed between the inner ring 12, 112 and outer ring 11, 111 is interpreted as a lumen according to Claim 72. However, in light of this interpretation, SHILEY fails to disclose structural feature d), i.e. SHILEY fails to disclose: "a lumen and valve prosthesis adapted to accommodate the valve prosthesis inside the lumen" and "a cylindrical outer body of the valve prosthesis, which fits in the lumen of the tubular element".

Claim 73 recites that, in the fixing position, the arms are located within the radial passages. This is not disclosed by SHILEY. According to SHILEY, the arms extend tangentially along the outer ring 11, but are not located within a radial passage

through outer ring 11 (or through inner ring 12). Thus, is claims 73 is further distinguishable from SHILEY.

Concerning claim 74, the arms of SHILEY extend in the tangential direction and do not extend in the longitudinal direction of the tubular element.

As to claim 77, the arms of SHILEY extend both in the insertion position as well as in the fixing position, in the tangential direction of the inner and outer rings. Thus, in the insertion position, the SHILEY arms do not point away from the surrounding vascular tissue.

Claim 72 defines the fixing and insertion position in relation to the fixing device. Subsequently Claim 88 defines:

i) that the arms and pins are bendable against a resilient force from the fixing position into the insertion position and fixable in this insertion position, and

ii) the fixing can be released in order to ensure the arms + pins bend back so that the fixing device returns automatically toward the fixing position under the influence of the resilient force.

In SHILEY, there is no release which allows an automatic return of the fixing device(inner ring 12 and outer ring 11 + pins and arms) toward the fixing position starting from the insertion position. This is because in SHILEY the inner and outer ring must be rotated with respect to each other in order to allow the pins to extend outwardly. This rotation of the rings must be

continued up to the pin that has been extended outwardly to its maximum. The fixing device does not automatically return, starting from the insertion position, toward the fixing position upon just upon release.

In this regard, SHILEY plainly fails to anticipate of render obvious the claimed invention.

As to claim 122, the radial passages 35 of SHILEY are not slit shaped. The passages 35 are bores. A bore is only open just at one or both longitudinal ends of the bore and is closed along its longitudinal side(s). A slit, as defined in Claim 122, however is open along a (entire) longitudinal side. Furthermore, the passages 35 do not extend in the longitudinal direction of the arms but perpendicular to the arms.

As to claims 123-124, the prosthesis fixing device of SHILEY comprises the inner ring, the outer ring, the arms and the pins. Taking into account that the pins are separate pieces of wire, which are not even fixed to the inner (or outer ring), but just inserted, these pieces of wire and inner/outer ring are not made of/from one piece as an integral whole.

Applicant believes that SHILEY also fails to disclose or suggest claim 125. As noted before, the inner ends of the wires of SHILEY are merely inserted in openings in the inner ring, these inner ends are not fixed to this inner ring. Thus, SHILEY does not disclose "said one end being fixed to the tubular element".

Furthermore, as discussed in an earlier reply to an office action, SHILEY does not disclose a (fixed) bend line for the arm. When going from the insertion position of Figure 5 of SHILEY to the fixing position of Figure 6 of SHILEY, the bending point of the wires shifts from close to the pointed free (outer) end 49 towards the inner end of the wire (lying in aperture 41), but as can be seen in Figure 6, this bending point will never reach or even get close to the respective aperture 41. This means that SHILEY does not disclose that the arms have one end fixed to the tubular element and (simultaneously) defining the bend line. The bend line thus is inherently also arranged at a fixed position, i.e. the position of fixation of the arm to the tubular element.

Concerning claim 126, the alleged arms of SHILEY extend, viewed along the arms starting from the tubular element, tangentially parallel to the tubular element (at the outside of the tubular element). The arms do not extend "obliquely" and most certainly do not extend "obliquely in radially inwards direction into the lumen".

The discussion in relation to claim 73 above also applies to claim 128. In addition, it is clear that SHILEY does not disclose that in the fixing position the arms are entirely located within these radial passages.

In view of the above, applicant asks that the rejection be withdrawn.

Claims 72-75, 77 and 78 and 122-124 were rejected under 35 USC 102(b) as allegedly being anticipated by STEVENS. This rejection is traversed.

Although this document discloses an assembly comprising a valve prosthesis and a prosthesis fixing device, this document does not disclose or suggest claim 72.

STEVENS discloses pins with pointed ends, but those pins are at any time located outside the tubular element. Those pins are not located inside any lumen of the tubular element.

Furthermore, the STEVENS' pins are not arranged on arms, but are directly fixed to the tubular element itself.

In STEVENS, the tubular element 85 is formed by a checked pattern of wires 90, wherein the wires (also called diagonals) are arranged diagonally and mutually crossing each other. With such a checked pattern of wires, the width of the meshes can be enlarged in one direction while simultaneously being reduced in the direction perpendicular to said one direction (see column 9, lines 25-29).

In the enclosed copy of drawing sheet 4 of STEVENS, applicant has introduced several labels and lines for the convenience of the Examiner.

Referring to Figures 13, 14 and to STEVENS, column 3 lines 25-33:

i) Figures 13a, 13b show the mounting ring in the closed/contracted condition (the insertion position of claim 72);

ii) Figures 14a, 14b show the mounting ring in the open/expanded condition (the inserted/fixing position of claim 72);

iii) A-Figures both show a side view of (a part of) the mounting ring; and

iv) B-Figures both show a cross-sectional view in the direction as indicated in the corresponding A-figures with arrows (see arrows 13b and 14b).

In the A-figures, one can see that the mounting ring is made as checked pattern of wires 90 (here called diagonals). As indicated by the arrows on the left, in between the A figures, the mounting ring can be enlarged from diameter D1 (fig 13b) to D2 (fig 14b) by enlarging the mesh width in the horizontal (circumferential) direction. Normally, this would result in reduction of the mesh width in the vertical (axial) direction. However, this is compensated for in STEVENS by flattening the diagonals 90, which are initially buckled (see figure 13b).

Furthermore, the axial ends of the diagonals are provided with pins. As follows from Figures 13b and 14b, the pins lie, both in the contracted (Fig 13b) as well as in the expanded (Fig 14b) condition, entirely at the outside of the mounting ring

(tubular element). The pins of STEVENS do not lie inside the lumen of the mounting ring.

With respect to claim 72 STEVENS thus clearly does not disclose an insertion position in which the pins are located essentially inside the lumen of the tubular element.

The diagonals 90 also stand in contrast to the claimed invention. As far as the entire pin is considered to consist of an arm part and a pin part, applicant notes:

i) this arm lies at any time at the outside of the tubular element (never inside); and

ii) this arm is not bended with respect to the tubular element when it goes from the insertion position to the fixing position;

The Examiner is also invited to compare claims 126 and 127, wherein in the insertion position, neither in the fixing position is this arm extended "obliquely in radially inwards direction into the lumen" and STEVENS does not disclose any position in which the pin approximately extends at right angles to the arm compare, respectively.

With respect to claim 73, STEVENS does not disclose "pins emerging through passages upon going from the insertion to the inserted/fixing position". This is because, in STEVENS, the pins lie at any time on the outside of the mounting ring. Moreover, as far as STEVENS discloses "radial passages", those passages (the meshes) are not suitable for allowing the pins to

emerge through upon going to the inserted/fixing position. The structural limitation of claim 73 that "the radial passages are, viewed in radial direction of the tubular element, located alongside the pins and arms" is not disclosed by STEVENS.

With respect to claim 88, it is observed that STEVENS clearly discloses that there is not "any bendability against a resilient force". At column 9, lines 26-30, STEVENS provides that an external pressure is required both to bring the mounting ring in the contracted condition as well as to bring it in the expanded condition. There is no use of resilient forces disclosed. Thus, STEVENS also fails to anticipate or render obvious the claimed invention.

As to claim 122, it is observed that the alleged 'passages' of STEVENS are checked-shaped and not slit-shaped.

With respect to claims 123 and 124, STEVENS states that the pins are separate elements secured by melding, welding or other connection methods (see col 9 lines 36-38). Thus, the mounting ring of STEVENS thus is not made from one part-piece.

In view of the above, it is believed to be apparent that STEVENS fails to disclose or suggest any of the claims.

Claims 72, 73, 88 and 122-124 were rejected under 35 USC 102(b) as allegedly being anticipated by MAGOVERN. This rejection is traversed.

MAGOVERN discloses an assembly comprising a valve prosthesis 26 and a prosthesis fixing device 2. The fixing

device is a ring having an inner wall 4 and outer wall 6. The inner wall 4 defines an axial passageway 8 into which the valve prosthesis can be accommodated. The fixing device/ring 2 is provided with a multiplicity of pins 20 distributed around the periphery of the ring 2. These pins have pointed ends 22 for penetrating a peripheral wall of the circulatory system. Furthermore, the fixing ring 2 of this assembly has an insertion position (Figures 1 and 3) and a fixing position (Figure 6). In the insertion position, the pins 20 do not extend beyond the outer wall 6 of the fixing ring 2 (see column 3 line 46-47), and in the fixing position the pins 20 project from the outside 6 of the fixing ring 2.

However, with respect to Claim 72, the MAGOVERN reference does not disclose:

i) pointed ends 22 of the pins penetrate the peripheral wall tissue in the fixing position (see figure 6, wherein the pointed ends are entirely accommodated inside the lip 14 at column 3, lines 65-67);

ii) pins 20 (and arms) are essentially located inside the lumen (axial passage 8) of the fixing ring 2 in the insertion position.

Figures 1 and 3 of MAGOVERN show the insertion position. One can see that about half of the pins 20 lies in the internal of the body of the ring 2. One can also measure from Figure 1 that the pins are from tip to head about 12 mm long and

that about 6 mm lies inside the lumen/axial passage 8 and the other about 6 mm lies in the radial passage 18 through the body of the ring 2.

Thus, only about half of the pins 20 lie, in the insertion position, inside the lumen (i.e., not essentially inside). If one were to follow the interpretation that the "basal parts of the pins 20" would be the arms, this would imply that the entire pin lies outside the lumen, when in the insertion position.

The pins(/arms) 20 are fixed by one end to the fixing ring (tubular element) via a bend line, in a manner permitting swinging around the bend line. The pins 20 are not fixed to the fixing ring. The pins 20 are received in a slideable manner in passages/channels 18 (see column 3, line 32) to be driven into the annulus by applying a force to the free inner ends of the pins.

Assuming, as the examiner does in his Office Action, that the "pin end 24" is the "arm" of Claim 72 or that the "basal half of pin 20" is the arm of Claim 72, the said "one end of the arm" is in both cases the "pin end 24". This "pin end 24" of MAGOVERN, is neither fixed nor does the pin comprise a bend line. As one can see in Figures 1, 3 and 6 of MAGOVERN, this "pin end 24" or the adjacent region of this "pin end 24" does not bend at all.

Taking into account that, in the insertion position, the pins of MAGOVERN extend in a radial direction and that, in the insertion position, the outer half of each pin 20 lies inside the radial passage 18, these radial passages 18 are not located alongside the pins and arms in the insertion position. Thus, MAGOVERN further fails to anticipate or render obvious claim 73.

As to claim 88, MAGOVERN discloses that the pins 20 can comprise super-elastic or shape-memory material in order to have a first linear form when, in the insertion position, constrained in the channel 18 and a second curved shape when, in the fixing position, extending from the outside of the ring 2, see column 3 lines 59-65.

However, Claim 72 defines the fixing and insertion position in relation to the fixing device. Moreover, claim 88 provides:

c) that the arms + pins are bendable against a resilient force from the fixing position into the insertion position and fixable in this insertion position, and

d) that the fixing can be released in order to ensure the arms and pins bend back so that the fixing device returns toward the fixing position under the influence of the resilient force.

In MAGOVERN, there is no release which allows an automatic return of the fixing device (ring 20) toward the fixing position starting from the insertion position. This is because in

MAGOVERN the pins 20 must be pushed radially outward in order to allow the outer half of the pins to curve. This radial pushing must be continued up to the pin has been pushed out to its maximum. The fixing device does not automatically return, starting from the insertion position, toward the fixing position upon just upon release. Thus, MAGOVERN fails to anticipate or render obvious the claimed invention.

MAGOVERN also fails to disclose or suggest claim 122. The radial passages 18 of MAGOVERN are not slit shaped. Those passages 18 are bores, as can be seen in Figures 4 and 5 of MAGOVERN. A bore is only open just at one or both longitudinal ends of the bore and is closed along its longitudinal side(s). A slit,as defined in Claim 122, however is open along a (entire) longitudinal side.

With respect to claims 123 and 124, it is observed that the pins 20 of MAGOVERN are separate elements not fixed to the ring 2 but slideably received in the ring. Thus, MAGOVERN's fixing device is not made of/from one part as an integral whole and it cannot be said that MAGOVERN anticipates or renders obvious these claims.

As to claim 125, the pins 20 in MAGOVERN are, in the insertion position, not fixed with one end to the ring 2. Neither, does MAGOVERN suggest a fixed end of the pin/arm which defines an, inherently fixed as well, bend line.

MAGOVERN fails to disclose claims 126 and 127. In MAGOVERN, the arms extend (if present), in the insertion position, perpendicular to the longitudinal axis of the ring, i.e. exactly in radial direction. The arms thus do not extend obliquely in radially inward direction. In this regard, the Examiner is respectfully reminded that Claim 72 requires that pointed ends of the pins face in radially outward direction, so that claim 126 provides that the arms and pointed ends of the pins extend, in the insertion position, in different directions at an angle with respect to each other. However, in MAGOVERN, the arms (if present) and the pins extend, in the insertion position, in the same straight linear direction.

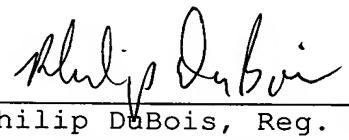
Accordingly,applicants believe that MAGOVERN fails to anticipate or render obvious any of the claims. Thus, applicant respectfully submits MAGOVERN fails to anticipate or render obvious any of the present claims.

In view of the present amendment and foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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APPENDIX:

- Copy of drawing sheet 4 of STEVENS, with labels and lines for further explanation in Figures 13 and 14.

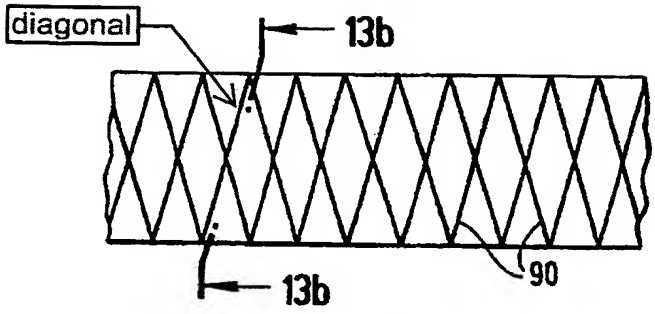

FIG. 13a

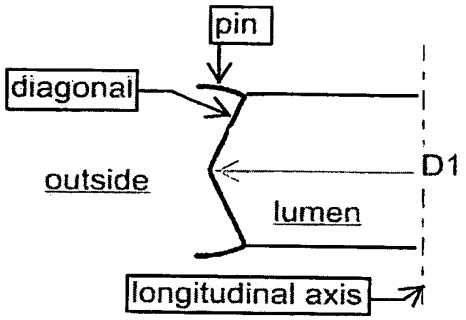

FIG. 13b

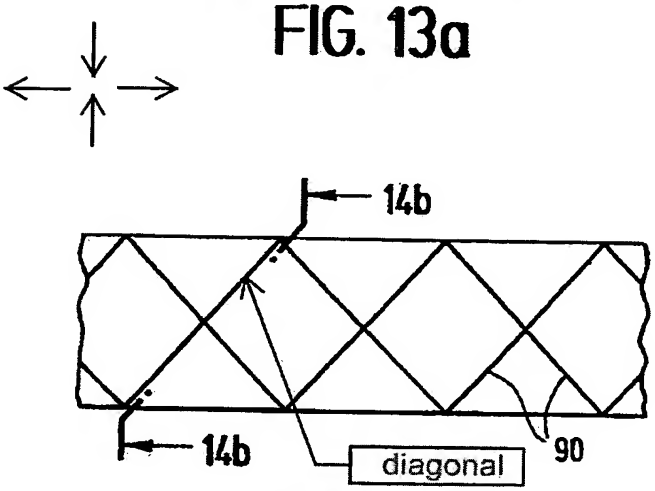

FIG. 14a

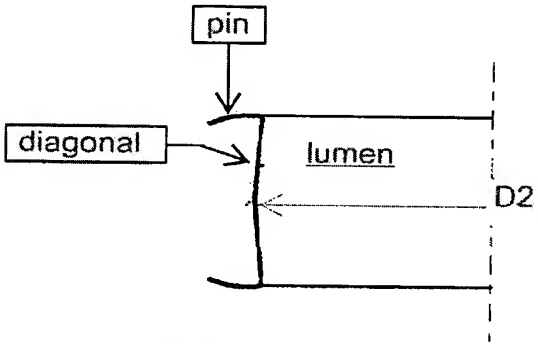

FIG. 14b

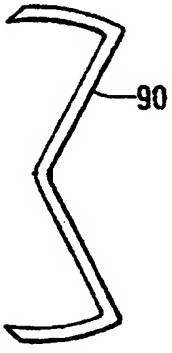

FIG. 15a

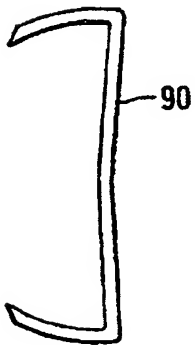

FIG. 15b